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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,458	02/11/2000	Michael R. Rosen	61020-A/HOW/PJP	6325

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01/15/2003

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,458

Applicant(s)

ROSEN ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Communication filed 12/4/02

1. Prior to this communication, claims 1-60 were pending in this application.

By this communication, the 35 U.S.C. 102(e) and 35 U.S.C. 103(a) rejections of record were traversed. The Applicant's comments have been fully considered and are addressed in paragraphs 2-4 of this action.

Claims 1-60 are pending in this application; claims 1, 12, 20, 31, 39, 50, 58, 59 and 60 are independent.

2. The Applicant states the instant invention is directed to prevent or reverse arrhythmias of many difference~~s~~ causes and the Ben-Haim et al. device is directed to improve cardiac failure, hence Ben-Haim et al. fails to disclose the methods of claims 1, 20 and 39 that remodel the gap junctions, induce ion channel remodeling, and alter the refractory period.

In response to Applicant's argument that Ben-Haim et al. do not disclose the methods of claims 1, 20 and 39 because the invention claimed by the Applicant and the invention by Ben-Haim et al. are directed to arrhythmias and cardiac failure respectively, it is noted these distinctions are not recited as elements in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The rejections of claims 1-60 are deemed proper.

3. The Applicant states Ben-Haim et al. fail to teach or suggest any aspect of remodeling gap junctions, altering the refractory period in the heart, or inducing ion channel remodeling.

In Paper No. 17 – paragraph 3, pertinent passages from US 6363279 to Ben Haim et al. are cited indicating disclosure related to remodeling gap junctions, altering the refractory period in the heart, and inducing ion channel remodeling. These citations are repeated below:

Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field ultimately modifying the action potentials, the ionic pumps and the channels of the heart (c 2, l 6 – c 3, l 32).

This invention focuses on controlling the heart by modifying the channels that connect the heart; the channels are read to include gap junction channels (c 2, l 6 – c 3, l 32). According to the Ben-Haim et al., these channels of the heart are modified by electrical stimulation (c 27, ll 12-27; c 27, ll 52-57; c 31, ll 1-5). While Ben-Haim addresses the controlling the channels of the heart, the gap junction channels are not specifically mentioned. It is however inherent that Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the art made of record, (Winslow et al. (US 5947899), c5, l 28 – c 6, l 3 and c 6, ll 33-53).

Refractory periods are modified by electrical stimulation (c 8, ll 3-5; c 8, l 66 – c 9, l 3; c 9, ll 15-19; c 17, ll 26-35; c 17, ll 45-46; c 31, ll 26-31; c 47, ll 37-45).

Ion channels are modified by electrical stimulation (c26, l 62 – c 27, l 27; c 27, ll 43-57; c 31, ll 1-5).

Changes in the heart occur over time as the heart is remodeled (c 9, ll 51-55; c 38, l 48 – c 39, l 10).

The rejections of claims 1-60 are deemed proper.

4. Based on the reasons of record and discussion in paragraphs 2 and 3 of this action, the 35 U.S.C. 102(e) and 35 U.S.C. 103(a) rejections of record are deemed proper and stand as noted in paragraphs 5-9 of this action.

Claim Rejections - 35 USC § 102

5. Claims 1, 9-11, 20, 28-30, 39 and 47-49 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ben-Haim et al. (US 6363279) for the reasons of record and the discussion in paragraphs 2-3 of this action.

Claim Rejections - 35 USC § 103

6. Claims 2, 5, 12, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308) for the reasons of record and the discussion in paragraphs 2-3 of this action.

7. Claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) and Edwards et al. (5681308) in view of Dahl et al. (US 5203348) for the reasons of record and the discussion in paragraphs 2-3 of this action.

8. Claims 7, 8, 26, 27, 45 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348) for the reasons of record and the discussion in paragraphs 2-3 of this action.

9. Claims 6, 16, 25, 35, 44 and 54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) and Edwards et al. (US 5681308) in view of Ideker (US 5873896) for the reasons of record and the discussion in paragraphs 2-3 of this action.

Conclusion

THIS ACTION IS MADE FINAL. The Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
1/12/03

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER
1/13/03